The pacemaker challenge

B. S. Goldman, M.D., F.R.C.S.[C], E. J. Noble, M.D., F.R.C.P.[C],
J. G. Heller, PH.D. and D. Covvey, M.SC., *Toronto*

We are confronted today by a scientific and social conundrum. Pacemaker therapy integrates the efforts of the bioelectronics industry, the clinical cardiac team and the community doctor, but, as well, creates intellectual and economic schisms that result in the failure of all to "deliver the goods" to the ultimate recipients, our patients.

Permanent pacemakers do rehabilitate and prolong life, but at the expense of patient anxiety[1] and frequent replacements, because of uncertain battery life, unpredictable component failure and the lack of interest on the part of unconcerned or unaware physicians. The time has now arrived for the recipient of pacemaker therapy to be also the beneficiary.

The insertion and replacement of pacemakers has become "big business" for both the electronics industry and the doctor in the United States. There, manufacturers' costs, surgical fees and the tariff for telephone surveillance are all highly inflated when compared with our own medical economy. The financial burden in our country, however, falls upon the ultimate provider, government health insurance programs. Although its curiosity has been whetted, our welfare giant has been slow to comprehend the expense of pacemaker therapy to this country and to its citizen-patients. National statistics concerning the growing indications for pacemaker implantation, the number of insertions and replacements, the average pacer longevity and the modes of follow-up in use, are generally unavailable. These could immediately reveal the high cost of pacemaker programs particularly in areas where no guidelines have been adequately established. There is a need in Canada to integrate and coordinate the efforts of manufacturer, physician and government to meet the pacemaker challenge.

The challenge to the manufacturer

1. Provide a reliable pacemaker with durable energy source, dependable components, predictable failure mode at reasonable cost.
2. Avoid a profusion of models and a confusion of terminology.
3. Avoid premature marketing of pacemakers, extravagant claims and pacing modes that merely bypass patent rights.
4. Allow adequate warranties to ensure confidence in the pacemaker and a return of investment to the consumer.
5. Ensure rapid, honest information on malfunctions, early failures, etc.
6. Participate in the education of patients and attending physicians.

Rapid developments in the electronics industry have introduced innovations making available new pacemaker rhythms and permitting new clinical applications. Continuing design changes have resulted in a profusion of pacemaker models and a confusion of terminology. It is difficult for even first-class pacemaker teams to keep abreast of changing pacemaker designs and the evolving indications for pacemaker therapy. One cannot help but suspect that there exists within the pacemaker industry the businessmen's approach to "the economics of obsolescence"; if the design and usage of cardiac pacemakers were stable, with dependable battery longevity, then fewer units would require replacement and sales and profits would therefore decrease. However, increasing complexity of pacemaker design plus increasing cost per unit ensure a constant financial reward to the industry for their dedication to circuitry.

No one has ever proved that people live longer with "demand" pacemakers than with "simple fixed-rate" units. The threat of competitive rhythms from asynchronous pacing is probably highly exaggerated, yet the cost of a simple fixed-rate unit is about $650.00 and can be lower. The cost of demand pacemakers runs about $900.00 per unit, and the cost of newer "standby" pacemakers with greater physiologic flexibility or greater (but unproved) longevity is now $1200.00 (e.g., pacemakers with external rate and current output control, or with conventional batteries with greater capacitance). Pacemakers with isotopic fuel for the energy source cost $5000.00 or more per unit — but in all fairness to the industry, longer warranties and fewer replacements may yield a greater return of investment than pacemakers with conventional battery power.

The challenge to the manufacturer is to provide a reliable pacemaker with a durable energy source and dependable components at a reasonable cost. Although much of the high cost of pacemakers does derive from continuing research and development and the maintenance of excellent quality control, the need to create design changes or technical differences simply to circumvent the patent rights of other manufacturers may add extra expense. This also can result in confusing nomenclature or introduce concepts that are not necessarily valid. For example, "rate hysteresis" has never been proved to prolong battery life by decreasing

From The Pacemaker Centre, Toronto General Hospital, Departments of Surgery and Medicine, University of Toronto

Presented in part to the Royal College of Physicians and Surgeons of Canada, Annual Meeting, Edmonton, Alta., January 1973

Supported in part by the Ontario Public Health Resources Fund, Demonstration Model #DM 116

Reprint requests to: Dr. B. S. Goldman, Toronto General Hospital, Toronto 2, Ont.

current drain. It was merely a mechanism by which certain manufacturers have avoided the patent rights on the original escape-interval of the initial demand concept.[2]

Manufacturers in general have attempted to meet their obligations to the medical community and to the patient in an honest manner and should not be faulted for their business needs. However, they could be freed of some of the encumbrances of patent protection which create much pacemaker confusion, and, as well, the potential medicolegal restrictions that delay accurate reporting of malfunction. Erroneous implications are created in both advertisements and the medical literature because of the need to bypass such encumbrances and restrictions.

The challenge to the government

1. Establish effective, appropriate medical devices legislation that ensures reliability and quality control but does not hinder medical progress.
2. Support clinical pacemaker research; validate pacing modes, indications for pacing, etc.
3. Encourage regional pacemaker clinics and support pacemaker therapy in smaller centres with adequate facilities and personnel.
4. Fund health economists and systems analysts to ensure adequate data acquisition, determine cost-effectiveness of pacemaker programs and economic impact on health insurance.
5. Establish a National Pacemaker Registry and a National Clinical Advisory Committee to collect vital statistics and conduct morbidity and longevity studies to determine appropriate pacemaker therapy for this country's citizen-patients.

In this country the government, acting as the health insurance carrier, is the ultimate provider of pacemaker goods. There are many areas of responsibility here that have yet to be covered or even defined. The American business and medical economy dictates the pacemakers we use and the types of follow-up needed, and therefore perhaps even the expanding indications for pacemaker implantation. Although a "Pacemaker Task Force" has been established by the health protection branch of the Department of National Health and Welfare, their frame of reference and their role in medical devices legislation is still uncertain. They have no clinical access or clinical experience, and could easily hinder progress by zealous bench testing, etc.

Government agencies should support clinical and experimental pacemaker research, and as well, should support pacemaker-patient care. In the Province of Ontario the Public Health Resources Fund has granted the Pacemaker Centre at the Toronto General Hospital a sum to develop regional pacemaker clinics throughout the province, utilizing trans-telephone relay of pacer data and a central computer file system for data retrieval and patient recall. This is a valuable way for the government to assist in the delivery of health care to the patient in his own community. None the less, the insurance carrier (OHIP) does not reimburse patients for the purchase of commercial telephone transmitters and it has therefore been necessary for this hospital to construct such devices.*

There is an urgent need for the government to assist the medical profession in validating the claims of manufacturers, to scrutinize and censor the sensational press so disturbing to pacemaker patients, and to ensure adequate electronic standards by effective and pertinent devices legislation.

However, government agencies must realize that in a field evolving so rapidly there is no statistical method by which a manufacturer can validate a pacemaker in animals or by bench tests carried out for a significant time period. Therefore each pacemaker implantation constitutes literally a human experiment and this is accepted by the medical community as ethical and appropriate for the patient's needs and our knowledge at any given time. The manufacturer should therefore be freed from the burden of medicolegal implications, from public disclosures regarding component difficulties, the need for recalls, etc.[3]

Most important would appear to be the need for a national pacemaker registry (established by either the Department of National Health and Welfare or the Medical Research Council) to ensure the collection of vital statistics from across Canada regarding this expensive form of therapy. Manufacturers are loath to disclose their sales in geographical areas; insurance carriers have unreliable figures regarding pacemaker inserts and replacements; and certainly few data are available for a study, on a nation-wide basis, on the original indications for pacer implant, the average pacer longevity, the alteration in patient life-span or the effect of newer pacer circuits and rhythms on the natural history of conduction disturbances. An epidemiologist and a systems analyst are associated with our own pacemaker centre to study the cost-effectiveness of pacemaker sur-

*Telephone transmitters (encoders) constructed by the Department of Medical Engineering and Biophysics of the Toronto General Hospital.

In the treatment of shock and its pulmonary complications

Solu-Medrol

soon enough, often enough, in pharmacologic doses

Dosage and Administration:

In treating severe shock, there is a tendency in current medical practice to use massive (pharmacologic) doses of corticosteroids. (The anti-inflammatory activity of 1 mg of Solu-Medrol is equal to 4 mg or more of hydrocortisone.)

The suggested dosage of Solu-Medrol for severe shock is 30 mg/kg stat and repeated in four hours, if necessary.

Therapy is initiated by administering Solu-Medrol intravenously over a period of at least ten minutes. In general, therapy should be continued only until the patient's condition has stabilized – usually not beyond 48 to 72 hours.

Solu-Medrol may be given by intravenous injection, by intravenous infusion, or by intramuscular injection. The preferred method for initial emergency use is intravenous injection.

Cautions: The general precautions and contraindications to systemic corticosteroid therapy should apply to the use of Solu-Medrol. However, when used for medical emergencies, or in shock-like states, the possible lifesaving effects must be weighed against the possible undesired hormonal effects. In the treatment of shock, Solu-Medrol should be adjunctive to conventional supportive therapy such as fluid replacement, etc. Although adverse effects associated with high-dose short-term corticoid therapy are uncommon, peptic ulceration may occur.

Supplied: In Mix-O-Vials containing Medrol (as methylprednisolone sodium succinate), 40 mg, 125 mg, 500 mg, and 1 g vials with water for injection.

References:

1. Wilson, J.W. (1972). Surg., Gynec. & Obstet., *134*:675.
2. Janoff, A. (1964). Shock, p. 93.
3. DeDuve, C. (1964). Injury, Inflammation and Immunity, p. 283.

PRODUCT OF Upjohn STEROID RESEARCH

MEMBER PMAC

738 REGISTERED TRADEMARK: MEDROL
TRADEMARKS: SOLU-MEDROL, MIX-O-VIAL
CE 6996.3

THE UPJOHN COMPANY OF CANADA
865 YORK MILLS ROAD / DON MILLS, ONTARIO

Bentylol

COMPOSITION

For antispasmodic action alone

1. Bentylol 10 mg. capsules, dicyclomine hydrochloride N.F.—10 mg. in each blue capsule.
2. Bentylol syrup, dicyclomine hydrochloride N.F.—10 mg. in each teaspoonful (5 ml.) pink syrup.
3. Bentylol Injection/Ampul—2 ml. Each 2 ml. contains 20 mg. dicyclomine hydrochloride N.F., in water for injection, made isotonic with sodium chloride.
   Vial—10 ml. Each 1 ml. contains 10 mg. dicyclomine hydrochloride N.F., in water for injection, made isotonic with sodium chloride and preserved with 0.5% chlorobutanol (chloral derivative).

For antispasmodic action plus sedation

1. ◈ Bentylol 10 mg. with Phenobarbital capsules, dicyclomine hydrochloride N.F.—10 mg. and phenobarbital—15 mg. in each blue and white capsule.
2. ◈ Bentylol 20 mg. with Phenobarbital tablets, dicyclomine hydrochloride N.F.—20 mg. and phenobarbital—15 mg. in each white tablet.
3. ◈ Bentylol with Phenobarbital syrup, dicyclomine hydrochloride N.F.—10 mg. and phenobarbital—15 mg. in each teaspoonful (5 ml.) of amber syrup. Alcohol 19%.

ACTIONS

Antispasmodic. Bentylol (dicyclomine hydrochloride) has a direct relaxant effect on smooth muscle as well as a depressant effect on parasympathetic function. These dual actions produce relief of spasm with minimum atropine-like side effects. Phenobarbital exerts a sedative effect.

INDICATIONS AND CLINICAL USE

Oral dosage forms

1. Symptomatic control of functional gastrointestinal disorders. Primary condition diagnosed as: chronic irritable colon, spastic constipation, mucous colitis, pylorospasm, biliary dyskinesia, or spastic colitis.
2. Gastrointestinal spasm secondary to organic diseases, such as: peptic ulcer, hiatal hernia, esophagitis, gastritis, duodenitis, cholecystitis, diverticulitis, and chronic ulcerative colitis.
3. Infants: Infant colic. (syrup form only.)

Injection form

Symptomatic treatment of the above conditions in adults when a rapid onset of therapeutic action is desired or when persistent nausea and vomiting preclude the use of oral administration.

CONTRAINDICATIONS

Dicyclomine hydrochloride is contraindicated in patients with frank urinary retention, stenosing peptic ulcer, and pyloric or duodenal obstruction.

PRECAUTION

Although studies have failed to demonstrate adverse effects of dicyclomine hydrochloride in glaucoma, it should be prescribed with caution in patients known to have or suspected of having glaucoma.

ADVERSE REACTIONS

Adverse reactions seldom occur with dicyclomine hydrochloride; however, in susceptible individuals, dry mouth or thirst and dizziness may occur. On rare occasions, fatigue, sedation, blurred vision, rash, constipation, anorexia, nausea and vomiting, headache, and dysuria have been reported. Phenobarbital may be habit forming.

With the injection form there may be a temporary sensation of lightheadedness and occasionally local irritation.

DOSAGE AND ADMINISTRATION

10 mg. Capsules or Syrup (plain and in combination with phenobarbital):
Adults—1 or 2 capsules or teaspoonfuls syrup three or four times daily.
Children—1 capsule or 1 teaspoonful syrup three or four times daily.
Infants—½ teaspoonful syrup three or four times daily. (May be diluted with an equal quantity of water.)

20 mg. Tablets with Phenobarbital:
Adults—1 tablet three or four times daily.

Injection—For intramuscular use only:
Adults—20 mg. (2 ml.) every four to six hours intramuscularly.

DOSAGE FORMS

10 mg. Capsules:
Bottles of 50 and 500

10 mg. Capsules with Phenobarbital:
Bottles of 24, 50, and 500

Syrup (plain and in combination with phenobarbital):
Bottles of 8 fl. oz. and 80 fl. oz.

20 mg. Tablets with Phenobarbital:
Bottles of 24 and 100

Injection:
2 ml. ampuls and 10 ml. multiple dose vials

Registered Trademark: Bentylol
Initial Printing March, 1971

1-057

Merrell

MEMBER PMAC

veillance, the correlation of therapy and patient mortality, and the economic impact on the provincial health insurance carrier (OHIP). Such a study of health economy should be funded through the national pacemaker registry within each province.

The challenge to the physician

1. Concerned physicians, not manufacturers or government agencies, should provide leadership in pacemaker therapy.
2. Pacemaker teams should act as liaison between government and manufacturers, to assist the former with health-economy problems and to ensure from the latter the highest integrity.
3. Physicians involved in the care of pacemaker patients should fully understand pacemaker terminology and function. They should educate and reassure their patients and educate the family physician.
4. Pacemaker teams must provide accurate data to manufacturers, and establish some mechanism of accurate surveillance to ensure patient security and maximum pacer longevity.

Pacemaker teams should themselves determine pacemaker therapy; neither the industry nor government task forces should be involved. Therefore, it is essential that the medical community act as the intermediary or liaison between manufacturer and government. We should not let industry dictate our policies nor can we let government interfere with our practice. To achieve this leadership role it is important that physicians caring for patients with pacemakers educate themselves fully in pacemaker circuitry, electrophysiology and terminology. They will then be able to discriminate between the pertinent information provided by a responsible manufacturer and the extravagant claims of an unreliable manufacturer.

It is necessary that the pacemaker team educate not only themselves but also the concerned patient and referring physician. University centres should evaluate pacing modes and validate the need for pacing in many of the more recently described conduction disturbances. As well, accurate means of data collection and retrieval and follow-up mechanisms for pacemaker surveillance must be established. In this regard it is imperative that pacemaker teams provide complete information to manufacturers since it is estimated that only 30 to 40% of all pacer implants have adequate data returned to the manufacturer.[3] Certain geographic areas could be encouraged to develop local pacemaker clinics for patient follow-up and replacement of failing pulse-generators after cooperative interchange of information with a larger centre. The implantation of permanent pacemakers on an occasional basis is a difficult problem to assess. There seems no reason, however, why a well-equipped hospital with intensive care facilities and interested cardiologists performing temporary pacemaker implantations in a coronary care situation, and a competent surgeon, should not be allowed to insert permanent pacemakers themselves. There is, of course, the obligation for self-education and perhaps the exchange of information with a peer group at a large volume pacemaker clinic. The "education" provided by the commercial salesmen of a pacemaker manufacturer is not adequate background for inserting or replacing pacemakers. No surgeon or cardiologist should embark upon a new pacemaker program unless he has already established some form of accurate pacemaker surveillance.[4] Over 50% of patients with implanted pacemakers are not followed up in any coordinated or efficient manner; this leads to unnecessary deaths, unnecessary replacements and, conversely, unnecessary premature replacements.[5]

Conclusion

There is a need to integrate and coordinate the electronics industry, the medical community and government agencies in this country to meet the challenge of pacemaker therapy; to ensure that integrity and reliability are not modified by a profit motive; to ensure that cardiac teams and community physicians are educated in both pacemaker function and follow-up; and to ensure that free, honest communication exists between government, manufacturer and physician to allow for continued rapid progress in pacemaker therapy. Unless each defines his individual areas of responsibility to meet the pacemaker challenge in a cohesive manner, governmental insurance or the budgets of insurance programs may hinder future development by slow, frustrating investigation and legislation of these costly bioelectronic devices. No one can then benefit.

References

1. Goldman BS, Noble EJ, MacGregor DC: Pacemaker panic. *Am J Cardiol* 30: 705, 1972
2. Furman S: The cardiac pacemaker and the manufacturer's responsibility. *Chest* 61: 411, 1972
3. Beall AC, Rainer WG: The cardiac pacemaker, the manufacturer and the surgeon. *Ibid*, p 413
4. Escher DJW, Furman S: Modern methods of follow-up of the patient with an implanted cardiac pacemaker. *Am J Cardiol* 28: 359, 1971
5. Noble EJ: *Management of the patient and his pacemaker*. Presented at the Ontario Heart Foundation Meeting, the Diagnosis and Management of Cardiovascular Disease, Toronto, Dec 7-8, 1972 (to be published)